

to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

#### SEC. 4. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”), in consultation with the Association of American Feed Control Officials, and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to feed, pet food, animal waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify contaminations of the pet food supply and outbreaks of illness from pet food. In establishing such system, the Secretary shall—

(A) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(B) consult with relevant professional associations and private sector veterinary hospitals; and

(C) work with Health Alert Networks and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out paragraph (1) such sums as may be necessary.

#### SEC. 5. SENSE OF THE SENATE.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion pets caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(B) an increasing volume of imported food, without adequate monitoring and inspection;

(4) the United States is increasing the amount of food that it imports such that—

(A) from 2003 to the present, the value of food imports has increased from \$45,600,000,000 to \$64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat and 78.6 percent of fish and shellfish; and

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional Food and Drug Administration inspectors are required if we are to improve Food and Drug Administration's ability to safeguard the food supply of the United States; and

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements, including memoranda of understanding, with the trading partners of the United States with respect to food safety.

#### SEC. 6. ANNUAL REPORT TO CONGRESS.

The Secretary of Health and Human Services shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products imported into the United States, aggregated by country, and type of food, if any;

(2) a listing of the number of inspectors of imported food products and the number of inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement mechanisms used to follow-up on such findings and violations.

### SUBMITTED RESOLUTIONS

#### SENATE CONCURRENT RESOLUTION 30—URGING ALL SIDES TO THE CURRENT POLITICAL CRISIS IN UKRAINE TO ACT RESPONSIBLY AND USE DIALOGUE TO RESOLVE THE CRISIS AND ENSURE A FREE AND TRANS-PARENT DEMOCRATIC SYSTEM IN UKRAINE BASED ON THE RULE OF LAW

Mr. DODD submitted the following concurrent resolution; which was referred to the Committee on Foreign Relations:

##### S. CON. RES. 30

*Resolved by the Senate (the House of Representatives concurring), That Congress—*

(1) acknowledges and welcomes the strong relationship formed between the United States and Ukraine since the restoration of Ukraine's independence in 1991;

(2) urges all sides to the current political crisis in Ukraine to act responsibly and use dialogue to resolve the crisis;

(3) urges all sides to adhere to the rule of law and resolve disputes in a peaceful manner consistent with Ukraine's democratic values and national interest, in keeping with its commitments as a member of the Organi-

zation for Security and Cooperation in Europe (OSCE);

(4) expresses strong and continuing support for the efforts of the Ukrainian people to establish a full democracy, the rule of law, and respect for human rights;

(5) pledges its continued assistance to the strengthening of a free and transparent democratic system in Ukraine based on the rule of law and the continued development of a free market economy in Ukraine; and

(6) reaffirms its commitment to Ukraine's independence, sovereignty and territorial integrity, and assumption of Ukraine's rightful place as a full member of the international community of democracies.

### AMENDMENTS SUBMITTED AND PROPOSED

SA 1008. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table.

SA 1009. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1010. Mr. COCHRAN (for himself, Mr. CARPER, Mr. NELSON, of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, supra.

SA 1011. Ms. STABENOW (for herself, Mr. THUNE, Mr. LOTT, Mr. BROWN, and Mr. KOHL) submitted an amendment intended to be proposed by her to the bill S. 1082, supra.

SA 1012. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1013. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1014. Mr. VITTER submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1015. Mr. HAGEL (for himself and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1016. Mr. SPECTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1017. Mr. GREGG (for himself and Mr. COLEMAN) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1018. Mr. DEMINT (for himself, Mr. INHOFE, Mr. BROWNBACK, Mr. MARTINEZ, Mr. VITTER, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, supra.

SA 1019. Mr. CASEY (for himself and Mr. SPECTER) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1020. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1021. Mrs. CLINTON submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1022. Mr. DURBIN (for himself, Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, Mr. KOHL, Ms. CANTWELL, Mr. SCHUMER, Mr. BIDEN, Mr. NELSON, of Florida, and Mr. CASEY) proposed an amendment to the bill S. 1082, supra.

SA 1023. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1024. Mr. SALAZAR submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1025. Mr. SCHUMER (for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY) proposed an amendment to the bill S. 1082, supra.

SA 1026. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1027. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1028. Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr. KOHL, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1029. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1030. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1031. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1032. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1033. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

#### TEXT OF AMENDMENTS

**SA 1008.** Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike section 252 and insert the following:  
**SEC. \_\_\_\_ . MARIJUANA SMOKED BY PATIENTS.**

(a) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary of Health and Human Services shall conduct an evaluation of the manufacture, distribution, and use of marijuana in States that have enacted laws legalizing, decriminalizing, or otherwise allowing the use of marijuana for purported medical use to determine—

(A) whether such activity is taking place in violation of any provision of Federal law for which the Department of Health and Human Services is responsible; and

(B) whether such marijuana activities are taking place in violation of any provision of

the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that is designed to ensure the safety and effectiveness of drugs used by the American public.

(2) REPORT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report concerning the findings of the evaluation conducted under paragraph (1).

(b) DETERMINATION OF EFFECTIVENESS.—Not later than 30 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall, based on available scientific data, make a determination, and disclose such determination to the general public, concerning—

(1) whether or not smoked marijuana is a safe or effective treatment for any medical condition; and

(2) the adverse impact to human health, both physician and mental, as a result of smoking marijuana.

**SA 1009.** Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title II, insert the following:

#### **Subtitle \_\_\_\_ Antibiotic Safety and Innovation** **SEC. 2 \_\_\_\_ . DEVELOPMENT OF ANTIMICROBIALS.**

(a) INCENTIVES FOR DEVELOPMENT OF NEW ANTIBIOTICS AND NEW ANTIBIOTIC USES.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

“(r)(1) Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an approved application described in paragraph (2) may elect to receive, with respect to the drug—

“(A)(i) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F); and

“(ii) the 5-year exclusivity period referred to under subsection (c)(3)(E)(ii) and under subsection (j)(5)(F)(ii); or

“(B) a patent term extension under section 156 of title 35, United States Code.

“(2) An application described under this paragraph is an application for marketing submitted under this section after the date of enactment of this subsection in which—

“(A) the drug that is the subject of the application contains an antibiotic drug; and

“(B) such antibiotic drug was the subject of an application received by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

“(3) Paragraph (1) shall not be construed to entitle a drug that is the subject of an approved application described in paragraph (2) for any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1).”.

(b) BIOEQUIVALENCE TO LISTED ANTIBIOTIC DRUG.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended by adding at the end the following:

“(D) Notwithstanding any other provision of this subsection, an oral antibiotic drug that is not intended to be absorbed into the bloodstream shall be considered to be bioequivalent to a listed antibiotic drug only if—

“(i) clinical trials do not show a significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness; or

“(ii) the Secretary has—

“(I) established alternative, scientifically valid methods that are reasonably expected to detect a significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness;

“(II) developed the alternative, scientifically valid methods described in subclause (I) through notice and comment rulemaking in accordance with section 553 of title 5, United States Code; and

“(III) determined that, based on the alternative, scientifically valid methods described in subclauses (I) and (II), there is no significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness.”.

(c) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting and, if appropriate, issue guidance regarding which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(d) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

“(c) For grants and contracts under subsection (a), there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2007, and \$35,000,000 for each subsequent fiscal year.”.

#### **SEC. 2 \_\_\_\_ . ESTABLISHMENT OF ANTIMICROBIAL BREAKPOINTS.**

(a) DEFINITION.—In this section, the term “antimicrobial breakpoint” means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested, such as Minimum Inhibitory Concentrations (MICs) or zones of inhibitions.

(b) ESTABLISHMENT OF BREAKPOINTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall direct the Commissioner of Food and Drugs to establish and periodically update antimicrobial breakpoints.

(2) REVIEW AND UPDATE.—Antimicrobial breakpoints shall be reviewed and updated as necessary pursuant to recommendations from the Antimicrobial Resistance Task Force and in consultation with the Centers for Disease Control and Prevention, or more frequently upon the discretion of the Commissioner of Food and Drugs, but in no case less than once every 5 years.

(c) PUBLIC AVAILABILITY.—The Secretary shall direct the Commissioner of Food and Drugs to make antimicrobial breakpoints publicly available within 30 days of the date of establishment and any update under this section.

(d) ADVISORY ORGANIZATIONS.—The Commissioner of Food and Drugs may contract with an organization or organizations to aid in the establishment of antimicrobial breakpoints under this section in a manner not inconsistent with the Federal Advisory Committee Act (5 U.S.C. App.). The Commissioner of Food and Drugs shall make the final determination regarding establishments of antimicrobial breakpoints under this section.

#### **SEC. 2 \_\_\_\_ . EXCLUSIVITY OF CERTAIN DRUGS CONTAINING ENANTIOMERS.**

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this subtitle, is amended by adding at the end the following: